DEC - 5 2011

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, MD Chief Medical Officer
Date Prepared:	September 6, 2011

DEVICE NAME

Trade/Proprietary Name:	Axle PEEK Interspinous Fusion System
Common Name(s):	Interspinous Process Fixation System
Classification Name(s):	Spinal Interlaminal Fixation Orthosis
Device Class:	Class II
Classification(s):	§888.3050
Product Codes(s):	KWP

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INTENDED USE

The Axle PEEK Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Axle PEEK Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

DEVICE DESCRIPTION

The Axle PEEK Interspinous Fusion System consists of plates and inserts of various sizes that are used to provide supplemental stabilization of the spinous processes to support fusion. The system components can be assembled in a variety of configurations so that adaptations can be made to take into account pathology and individual patient anatomy. The implant components are provided clean and non-sterile.

The plate components of the device are made from titanium alloy per ASTM F136 and the insert components are made from polyetheretherketone (Invibio PEEK-Optima LT1).

COMPARISON TO CLEARED DEVICE

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Axle PEEK Interspinous Fusion System substantially meets the performance criteria established by the cleared parent device. The modified device is substantially equivalent to predicate device based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Product Dimensions
- Mechanical Performance

PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F1717 – *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*

- Static Compression Bending
- Static Torsion
- Fatigue Compression Bending

In conclusion, biomechanical testing results indicate that the Axle PEEK Interspinous Fusion System is substantially equivalent to predicate device performance and is capable of safely and effectively performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 5 2011

X-spine Systems, Inc.
% David Kirschman, MD
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K112592
Trade/Device Name: Axle PEEK Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: November 04, 2011
Received: November 07, 2011

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112592

Device Name: Axle PEEK Interspinous Fusion System

Indications for Use:

The Axle PEEK Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Axle PEEK Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112592